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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,726	12/21/2001	Wen-Hwa Lee	17726A-000420US	4418

20350 7590 02/13/2004

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EXAMINER
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WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/028,726

Applicant(s)

LEE ET AL.

Examiner

Michael C. Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 49-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Sequence Listing***

The amino acid sequence in Table 1 was described on pg 27, line 15, in the amendment to ¶ 152 filed 2-20-03 on pg 3.

On Pg 44, the amino acid and nucleic acid sequences in Table 4 were described in the amendment to ¶ 225 filed on 2-20-03. It is noted that the amendment filed 2-20-03 used the wrong page number to describe ¶ 225. The amendment filed 11-17-03 does not use any page or line number to describe the paragraphs. Please use the page and line number to describe the beginning of paragraphs being amended.

### ***Priority***

The claims have support in claims 41-47 as originally filed, and pg 43, 1<sup>st</sup> ¶. Claims 41-47 as originally filed can also be found in 07/265,829 and suppression of the neoplastic phenotype is found on pg 53, line 1, of '829.

### ***Specification***

The status of application 08/472,760 on pg 1, line 1, will have to be updated as necessary.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

1. Claims 49-56 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

Applicants (Wen-Hwa Lee, Huie-Jen Su Huang, and Eva Y.H.P. Lee) claim a method of treating mammalian cancer cells lacking endogenous wild-type RB protein by introducing a wild-type RB gene into the cells, thereby suppressing the cells' neoplastic phenotype. Wen-Hwa Lee and Phang-Lang Chen (US Patent 5,532,220) invented a method of treating mammalian cancer cells lacking endogenous wild-type p53 protein by introducing a wild-type p53 gene into the cells, thereby suppressing the cells' neoplastic phenotype. The claims of '220 encompass of the methods claimed in the instant application. Applicants must provide evidence that Lee, Huang and Eva Lee invented the claimed invention and not Lee and Chen.

2. Claims 49-56 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

Applicants (Wen-Hwa Lee, Huie-Jen Su Huang, and Eva Y.H.P. Lee) claim a method of treating mammalian cancer cells lacking endogenous wild-type RB protein by introducing a wild-type RB gene into the cells, thereby suppressing the cells' neoplastic phenotype. The inventive entity in the instant application is incorrect because Dr. Theodore Friedmann and Dr. Jiing-Kuan Yee designed the vector encoding RB for treating cancer cells as claimed. The design of a vector for gene therapy was known at the time of filing to be essential to obtain the desired effect. Dr. Friedmann and Dr. Yee determined the elements of the vector required to obtain adequate and stable expression of RB (see declarations by Dr. Theodore Friedmann and Dr. Jiing-Kuan Yee

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filed 12-21-01). Therefore, Wen-Hwa Lee, Huie-Jen Su Huang, and Eva Y.H.P. Lee did not invent the claimed subject matter alone.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 49-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,532,220. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treating mammalian cancer cells lacking endogenous wild-type p53 protein by introducing a wild-type p53 gene into the cells, thereby suppressing the cells' neoplastic phenotype in '220 is a species of the method of treating mammalian cancer cells lacking endogenous wild-type RB protein by introducing a wild-type RB gene into the cells, thereby suppressing the cells' neoplastic phenotype as claimed in the instant application. Claims 51-56 are equivalent to claims 3-6 of '220.

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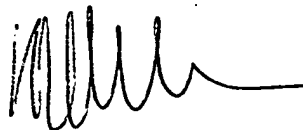
Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at 571-272-0738.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson

A handwritten signature in black ink, appearing to read 'Michael C. Wilson', with a stylized, cursive script.

**MICHAEL WILSON  
PRIMARY EXAMINER**